

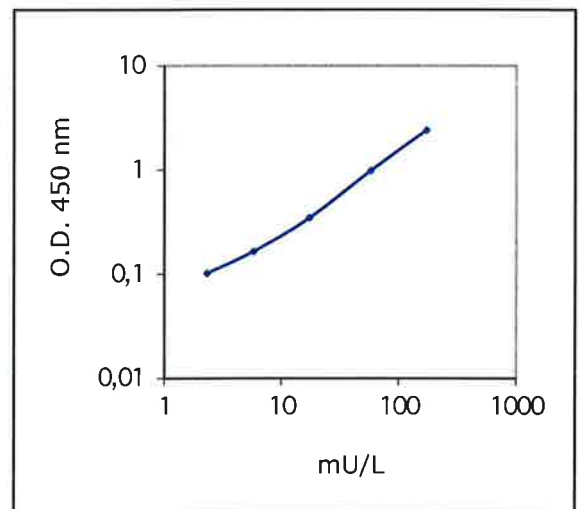
## Certificate of Analysis

### 1. Manufacturer

Mercodia AB, Sylveniusgatan 8A, 754 50 Uppsala, SWEDEN

### 2. Description

Catalog no: 10-1205-01  
Product: Mercodia Equine Insulin ELISA  
Lot no: 32442  
Expiry date: 2024-02-29



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-5325	32094	0,065	2024-03-11
Calibrator 2,3 mU/L	20-5320	32085	0,102	2024-03-09
Calibrator 5,8 mU/L	20-5321	32086	0,165	2024-03-09
Calibrator 17 mU/L	20-5322	32087	0,347	2024-03-09
Calibrator 58 mU/L	20-5323	32088	0,987	2024-03-09
Calibrator 173 mU/L	20-5324	32089	2,482	2024-03-09
Coated Plate	20-5272	32091		2024-03-15
Enzyme Conjugate 11X	20-5314	32100		2024-03-11
Enzyme Conjugate Buffer	20-5305	32096		2024-03-10
Wash Buffer 21X	20-6746	32003		2028-02-12
Substrate TMB	20-2629	31053		2024-07-31
Stop Solution	20-2693	32068		2028-02-25

### 3. Quality control

Quality control has been performed for lot no 32442 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

### 4. Calibration

The Mercodia Equine Insulin ELISA is calibrated against an in-house reference preparation of porcine insulin.

### 5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

### 6. Intended use

Mercodia Equine Insulin ELISA provides a method for the quantitative determination of equine insulin in serum or plasma.

### 7. Storage and handling

Recommended storage of kit is 2-8°C.  
Storage of unused or diluted kit components is stated in the Direction for Use.

### 8. Hazardous information

Please refer to the Material Safety Data Sheet for hazard identification.

### 9. Quality standard documentation

The Mercodia Quality System fulfills the QSR and the requirements for the European CE mark, the Directive 98/79/CE on *in vitro* diagnostic medical devices. Mercodia is ISO 13485 certified, for compliance with the International Quality Management System for medical devices.

### 10. Names and signatures of certifying officers

Date of analysis:	Performed by:	Signature:
<u>2021-05-21</u>	<u>Linnéa Forslund</u>	<u>[Signature]</u>

Date of approval:	Approved by:	Signature:
<u>2021-05-24</u>	<u>Elin Westberg</u>	<u>[Signature]</u>